



Blue Cross of California

Rob Seidman, Pharm.D., M.P.H.
Vice President
Blue Cross of California Pharmacy

2510 '99 MAY -4 AM 103

April 30, 1999

Food and Drug Administration
Center for Drug Evaluation and Research (HFD-21)
ATTN: Gloria Ortega
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Ortega:

In support of FDA docket number 98P-0610/CP, we have recently obtained copies of reported adverse drug events for over-the-counter non-sedating antihistamines available in Canada. A search of the entire Canadian national database was performed for all suspected adverse events associated with over-the-counter non-sedating antihistamines. All information provided is current from each drug's date of initial marketing through April 12, 1999. The Continuing assessment Division of the Bureau of Drug Surveillance in Canada provided the reports. It is important to note that the reports provided to the Bureau have not been scientifically or otherwise verified as to the cause and effect relationship between the drugs taken and their potential negative impact on the patient.

Of the million of over-the-counter antihistamine doses dispensed in Canada, the Canadian Bureau of Drug Surveillance received 79 potential incidents of a drug interaction for fexofenadine, 94 for loratadine and 43 for cetirizine. In the majority of these cases where a suspected adverse drug reaction occurred, the patient recovered without any impairment. In all cases, the relationship between the drug and the reported adverse event could not be established.

In support of docket number 98P-0610/CP, I request that the FDA review the over-the-counter safety data compiled by the Canadian Bureau of Drug Surveillance. In addition, please review the safety data in the direct to over-the-counter Canadian drug approvals for loratadine, fexofenadine and cetirizine.

Thank you,

Robert Seidman

cc: Andrea Masciale

98P-0610

SUP 1

Health Santé
Canada Canada



PROGRAMME DES
P R O D U I T S
THERAPEUTIQUES
THERAPEUTIC
P R O D U C T S
PROGRAMME

Part I: 23 pages + this one
Part II: 19 pages + this one
Part III: 19 pages + this one

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

OUR MISSION: To ensure that the drugs, medical devices and other therapeutic products available in Canada are safe, effective and of high quality.

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CONTINUING ASSESSMENT DIVISION / DIVISION DE L'ÉVALUATION CONTINUE
BUREAU OF DRUG SURVEILLANCE / BUREAU DE LA SURVEILLANCE DES MÉDICAMENTS
FINANCE BUILDING / ÉDIFICE FINANCE
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OTTAWA (ONTARIO)
K1A 1B9
ADDRESS LOCATOR -0201C1 - INDICE DE L'ADRESSE
FAX: (613) 957-0335

TO/À: Robert Seidman

FAX: 1(818) 712-6482

TEL: (818) 610-4817

DATE: April 13, 1999

NUMBER OF PAGES TO FOLLOW: 61

NOMBRE DE PAGES À SUIVRE:

MESSAGE/MESSAGE:

Dear Mr. Seidman,

This is further to your fax dated December 16, 1998 requesting information on suspected adverse drug reactions (ADRs) associated with the use of cetirizine, fexofenadine and loratadine. We apologize for the delay.

A search of the national database was performed for all the suspected adverse reactions associated with these suspected drugs. The attached printouts outline the results. These printouts cover the time period since marketing until April 12, 1999. There may be reports which have been received by the program which are not yet entered into the database. Kindly direct your attention of all persons using these printouts to the following Caveat:

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Protection Branch is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Protection Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization.

If you have any further questions, please do not hesitate to contact me.

Pascale Springuel

RECEIVED TIME APR.13. 11:31AM

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0066744	LORATADINE System Organ Class: METABOLIC AND NUTRITIONAL DISORDERS CALCIUM SUPPLEMENT VITAMIN C VITAMIN E	64 Year(s)	Female		02 Month(s)	Suspected Concomitant Concomitant Concomitant	10.00 Milligrams 1 Daily WHO Adverse Reaction Term: WEIGHT INCREASE 500.0 Milligrams 3 Daily 500.0 Milligrams 1 Daily 400.0 Milligrams 1 Daily	Recovered without sequelae
0067394	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS BODY AS A WHOLE - GENERAL DISORDERS PSYCHIATRIC DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS VISION DISORDERS RESPIRATORY SYSTEM DISORDERS PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS HISMANAL SELDANE	57 Year(s)	Male		08 Day(s)	Suspected Other Other	10.00 Milligrams 1 Daily WHO Adverse Reaction Term: AGITATION ANAPHYLACTOID REACTION ANOREXIA DYSPHAGIA VISION BLURRED DYSPNOEA IRRITABILITY FAINTNESS 10.00 Milligrams 1 Daily 60.00 Milligrams 2 Daily	Recovered without sequelae
0068518	CLARITIN System Organ Class: MUSCULO-SKELETAL SYSTEM DISORDERS AMITRIPTYLINE	30 Year(s)	Female		02 Day(s)	Suspected Concomitant	10.00 Milligrams 1 Daily WHO Adverse Reaction Term: MYALGIA 50.00 Milligrams 1 Daily	Recovered without sequelae
0069857	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS CHOLEDYL	63 Year(s)	Female			Suspected Concomitant	10.00 Milligrams WHO Adverse Reaction Term: NIGHTMARES 100.0 Milligrams	Recovered without sequelae

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April 12, 1999

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RECEIVED TIME APR.13. 11:31AM

APR 13 1999 14:31
BUREAU OF DRUG SURVEILLANCE
613 957-0335
10 1818 7126482
F.02/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0070678	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS	40 Year(s)	Male			Suspected	1.00 Dosage form	Recovered without sequelae
0070843	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS METAMUCIL	74 Year(s)	Male		01 Day(s)	Suspected Concomitant	10.00 Milligrams TACHYCARDIA ATRIAL 10.00 Millicurie 2 Daily	Recovered without sequelae
0073162	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS VASCULAR (EXTRACARDIAC) DISORDERS VISION DISORDERS	40 Year(s)	Female			Suspected	WHO Adverse Reaction Term: TACHYCARDIA FLUSHING ACCOMMODATION ABNORMAL	Recovered without sequelae
0073942	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS HEART RATE AND RHYTHM DISORDERS ORUDIS PENGLOBE	36 Year(s)	Male		01 Day(s) 02 Day(s) 04 Day(s)	Suspected Concomitant Concomitant	10.00 Milligrams WHO Adverse Reaction Term: INSOMNIA TACHYCARDIA 200.0 Milligrams 400.0 Milligrams 2 Daily	Recovered without sequelae

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RECEIVED TIME APR. 13. 11:31AM

APR 13 1999 14:32
BUREAU OF DRUG SURVEILLANCE
613 957-0335
TOLL FREE 1-818-126482
P.03/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0074381	CLARITIN <i>System Organ Class:</i> SKIN AND APPENDAGES DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS MUSCULO-SKELETAL SYSTEM DISORDERS SKIN AND APPENDAGES DISORDERS PREMARIN PREDNISONE	70 Year(s)	Female		01 Day(s)	Suspected Concomitant Treatment	1.00 Dosage form 1 Daily <i>WHO Adverse Reaction Term:</i> RASH ERYTHEMATOUS DIZZINESS OEDEMA OF EXTREMITIES JOINT SWELLING NON-INFLAMMATORY PRURITUS 30.00 Milligrams	Recovered without sequelae
0076929	CLARITIN <i>System Organ Class:</i> METABOLIC AND NUTRITIONAL DISORDERS VISION DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS CENTRUM ESTROGENS TEA	50 Year(s)	Female		03 Day(s) 13 Day(s) Continuing on Drug 01 Week(s)	Suspected Concomitant Concomitant Concomitant	10.00 Milligrams <i>WHO Adverse Reaction Term:</i> DEHYDRATION EYE ABNORMALITY MOUTH DRY 1.00 Dosage form 1.00 Dosage form	Not yet recovered
0078195	CLARITIN <i>System Organ Class:</i> BODY AS A WHOLE - GENERAL DISORDERS PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS	72 Year(s)	Female			Suspected	10.00 Milligrams 2 Daily <i>WHO Adverse Reaction Term:</i> CHEST DISCOMFORT ANOREXIA DIZZINESS MALAISE NAUSEA	
0079176	CLARITIN <i>System Organ Class:</i> PSYCHIATRIC DISORDERS	55 Year(s)	Female		04 Day(s)	Suspected	 <i>WHO Adverse Reaction Term:</i> INSOMNIA	Recovered without sequelae

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APR 13 '99 14:32 FR B DRUG SURVEILLANCE 613 957 0335 TO 18187126482 P.04/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME

APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0079581	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS VENTOLIN	41 Year(s)	Female			Suspected WHO Adverse Reaction Term: PERSONALITY DISORDER Concomitant	1.00 Dosage form	Recovered without sequelae
0081473	CLARITIN System Organ Class: SKIN AND APPENDAGES DISORDERS SKIN AND APPENDAGES DISORDERS BECLOVENT INHALER VENTOLIN FOR INHALATION HYDROCORTISONE	40 Year(s)	Female			Suspected WHO Adverse Reaction Term: PRURITUS URTICARIA Concomitant Concomitant Treatment	1.00 Dosage form	Recovered without sequelae
0081772	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS	60 Year(s)	Male		04 Day(s)	Suspected WHO Adverse Reaction Term: TACHYCARDIA	10.00 Milligrams	Recovered without sequelae
0081773	CLARITIN System Organ Class: URINARY SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS LOPID	36 Year(s)	Male			Suspected WHO Adverse Reaction Term: URINARY RETENTION MOUTH DRY Concomitant	10.00 Milligrams 2 Daily 1200 Milligrams	Recovered without sequelae
0081875	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS CONJUGATED ESTROGENS	45 Year(s)	Female			Suspected WHO Adverse Reaction Term: PALPITATION Concomitant	1.00 Dosage form 0.62 Milligrams 1 Daily	

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APR 13 1999 14:32 HR B DRUG SURVEILLANCE 613 957 0335 10 1818126#02

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME
APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0081975	CLARITIN System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS	29 Year(s)	Female			Suspected WHO Adverse Reaction Term: PARAESTHESIA	10.00 Milligrams 1 Daily	Recovered without sequelae
0082427	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS NOVOSPIROTON RIVOTRIL		Female		01 Day(s)	Suspected WHO Adverse Reaction Term: NAUSEA HEADACHE DIZZINESS CHILLS Concomitant Concomitant	1.00 Dosage form 1 Daily 100.0 Milligrams As necessary 0.50 Milligrams 2 Daily	Recovered without sequelae
0082533	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS	52 Year(s)	Male			Suspected WHO Adverse Reaction Term: ABDOMINAL PAIN	10.00 Milligrams 1 Daily	Recovered without sequelae
0082534	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS ZANTAC	45 Year(s)	Female			Suspected WHO Adverse Reaction Term: DYSPEPSIA Treatment	10.00 Milligrams 150.0 Milligrams	Recovered without sequelae
0083443	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS ISOPTIN VERAPAMIL HYDROCHLORIDE I	47 Year(s)	Female		05 Month(s)	Suspected WHO Adverse Reaction Term: TACHYCARDIA CONDITION AGGRAVATED Other Treatment	10.00 Milligrams 240.0 Milligrams	Recovered without sequelae

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APR 13 '99 14:33 FR B DRUG SURVEILLANCE 613 957 0335 TO 18187126482 P.06/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into data base before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0083826	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS HEART RATE AND RHYTHM DISORDERS	38 Year(s)	Male			Suspected WHO Adverse Reaction Term: ARRHYTHMIA PALPITATION	10.00 Milligrams	Recovered without sequelae
0083845	CLARITIN System Organ Class: PLATELET,BLEEDING & CLOTTING DISORDERS	7 Year(s)	Male		01 Day(s)	Suspected WHO Adverse Reaction Term: EPISTAXIS	5.00 Milligrams	Recovered without sequelae
0084067	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS PULMICORT INHALER THEOPHYLLINE VENTOLIN	41 Year(s)	Male		01 Day(s)	Suspected WHO Adverse Reaction Term: HALLUCINATION DIZZINESS Concomitant Concomitant Concomitant	10.00 Milligrams 1 Daily As necessary 600.0 Milligrams As necessary	Recovered without sequelae
0084068	CLARITIN System Organ Class: RESPIRATORY SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS CARDIOVASCULAR DISORDERS, GENERAL BODY AS A WHOLE - GENERAL DISORDERS	45 Year(s)	Male		01 Day(s)	Suspected WHO Adverse Reaction Term: DYSпноEA CHEST PAIN OEDEMA DEPENDENT ALLERGIC REACTION	10.00 Milligrams 1 Daily	
0084069	CLARITIN System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS	29 Year(s)	Female		01 Day(s)	Suspected WHO Adverse Reaction Term: PARAESTHESIA	10.00 Milligrams	Recovered without sequelae

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APR 13 '99 14:33 FR B DRUG SURVEILLANCE 613 957 0335 TO 18187126482 P. 07/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0084070	CLARITIN System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS	48 Year(s)	Female		05 Year(s)	Suspected WHO Adverse Reaction Term: PARAESTHESIA		Not yet recovered
0084071	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS BECONASE PREMARIN	42 Year(s)	Female		10 Day(s)	Suspected WHO Adverse Reaction Term: PARONIRIA Concomitant Concomitant	10.00 Milligrams 2.00 Dosage form 2 Daily 0.62 Milligrams	Not yet recovered
0084080	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS BODY AS A WHOLE - GENERAL DISORDERS	24 Year(s)	Male		01 Day(s)	Suspected WHO Adverse Reaction Term: HALLUCINATION DROWSINESS FATIGUE	1.00 Dosage form	Recovered without sequelae
0084116	CLARITIN EXTRA System Organ Class: HEART RATE AND RHYTHM DISORDERS CARDIOVASCULAR DISORDERS, GENERAL VASOTEC	49 Year(s)	Male		02 Day(s)	Suspected WHO Adverse Reaction Term: PALPITATION HYPERTENSION Treatment	5.00 Milligrams 2 Daily	Recovered without sequelae
0084118	CLARITIN System Organ Class: METABOLIC AND NUTRITIONAL DISORDERS		Male			Suspected WHO Adverse Reaction Term: OEDEMA PERIORBITAL	10.00 Milligrams	Recovered without sequelae
0084191	CLARITIN EXTRA System Organ Class: MUSCULO-SKELETAL SYSTEM DISORDERS	44 Year(s)	Male		02 Day(s)	Suspected WHO Adverse Reaction Term: ARTHRALGIA	1.00 Dosage form	Recovered without sequelae

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APR 13 '99 14:33 FR B DRUG SURVEILLANCE 613 957 0335 TU 18187126482 P.08/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0084372	CLARITIN System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS HEART RATE AND RHYTHM DISORDERS	47 Year(s)	Female		01 Day(s)	Suspected WHO Adverse Reaction Term: SHAKING ARRHYTHMIA	10.00 Milligrams	Recovered without sequelae
0084373	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS	55 Year(s)			01 Day(s)	Suspected WHO Adverse Reaction Term: EUPHORIA PERSONALITY DISORDER TREMOR LIMB	10.00 Milligrams 2 Daily	Recovered without sequelae
0084374	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS ROBITUSSIN-DM	9 Year(s)	Female		01 Day(s) 09 Day(s)	Suspected WHO Adverse Reaction Term: SLEEP DISORDER Concomitant	1.00 Teaspoonful 1.00 Teaspoonful	Not yet recovered
0084477	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS		Female			Suspected WHO Adverse Reaction Term: ABDOMINAL DISCOMFORT DIARRHOEA	10.00 Milligrams 1 Daily	Recovered without sequelae
0084478	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS		Female			Suspected WHO Adverse Reaction Term: ABDOMINAL DISCOMFORT	10.00 Milligrams 1 Daily	Recovered without sequelae
0085161	CLARITIN System Organ Class: SKIN AND APPENDAGES DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS PSYCHIATRIC DISORDERS	78 Year(s)	Female		01 Day(s)	Suspected WHO Adverse Reaction Term: SWEATING INCREASED ABDOMINAL PAIN ANOREXIA	5.00 Milligrams	Recovered without sequelae

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APR 13 '99 14:34 FR B DRUG SURVEILLANCE 613 957 0335 TO 18187126482 P.09/24

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0085651	CLARITIN System Organ Class: BODY AS A WHOLE - GENERAL DISORDERS	76 Year(s)	Female			Suspected WHO Adverse Reaction Term: CHEST TIGHTNESS OF	1.00 Dosage form 1 Daily	
0085839	CLARITIN System Organ Class: URINARY SYSTEM DISORDERS HYTRIN	54 Year(s)	Male			Suspected WHO Adverse Reaction Term: URINARY RETENTION Concomitant	10.00 Milligrams	Recovered without sequelae
0086074	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS	24 Year(s)	Male		01 Day(s)	Suspected WHO Adverse Reaction Term: EMOTIONAL LABILITY	10.00 Milligrams 1 Daily	Recovered without sequelae
0086445	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS		Female		19 Day(s)	Suspected WHO Adverse Reaction Term: DYSPEPSIA PARAESTHESIA NAUSEA	1.00 Dosage form 1 Daily	Recovered without sequelae

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Summary of Reported Adverse Drug Reactions
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All Reports received and entered into database before April 12, 1999

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086756	CLARITIN	12 Year(s)	Male		13 Day(s)	Suspected	10.00 Milligrams Daily	Died drug may be contributory
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	GASTRO-INTESTINAL SYSTEM DISORDERS					VOMITING		
	BODY AS A WHOLE - GENERAL DISORDERS					MALAISE		
	BODY AS A WHOLE - GENERAL DISORDERS					WEAKNESS GENERALIZED		
	PLATELET,BLEEDING & CLOTTING DISORDERS					EMBOLISM MESENTERIC		
	RESPIRATORY SYSTEM DISORDERS					PULMONARY HAEMORRHAGE		
	PSYCHIATRIC DISORDERS					SEDATION		
	URINARY SYSTEM DISORDERS					RENAL FAILURE ACUTE		
	LIVER AND BILIARY SYSTEM DISORDERS					HEPATIC FAILURE		
	LIVER AND BILIARY SYSTEM DISORDERS					BUDD CHIARI SYNDROME		
	GASTRO-INTESTINAL SYSTEM DISORDERS					EPIGASTRIC PAIN NOT FOOD-RELATED		
	HEART RATE AND RHYTHM DISORDERS					CARDIAC ARREST		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					ENCEPHALOPATHY		
	LIVER AND BILIARY SYSTEM DISORDERS					HEPATIC NECROSIS		
	CARDIOVASCULAR DISORDERS, GENERAL					HYPERTENSION		
	PLATELET,BLEEDING & CLOTTING DISORDERS					PROTHROMBIN TIME PROLONGED		
	PLATELET,BLEEDING & CLOTTING DISORDERS					THROMBOCYTOPENIA		
	NEOPLASM					HAEMOGLOBIN INCREASED		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA		
	LIVER AND BILIARY SYSTEM DISORDERS					HEPATOMEGALY		
	RESPIRATORY SYSTEM DISORDERS					RESPIRATORY RATE INCREASED		
	LIVER AND BILIARY SYSTEM DISORDERS					VENOOCCLUSIVE LIVER DISEASE		
	METABOLIC AND NUTRITIONAL DISORDERS					DEHYDRATION		
	CHEMOTHERAPY					Treatment		
0086781	CLARITIN	32 Year(s)	Male			Suspected	10.00 Milligrams As necessary	Recovered without sequelae
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	NEOPLASM					CARCINOMA		

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086791	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS	45 Year(s)	Male			Suspected WHO Adverse Reaction Term: PALPITATION	1.00 Dosage form 1 Daily	Recovered without sequelae
0086960	CLARITIN System Organ Class: SKIN AND APPENDAGES DISORDERS PREDNISONE	20 Year(s)	Male			Suspected WHO Adverse Reaction Term: RASH Treatment	30.00 Milligrams 1 Daily	Recovered without sequelae
0087080	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS REPRODUCTIVE DISORDERS, MALE	41 Year(s)	Male			Suspected WHO Adverse Reaction Term: IMPOTENCE EJACULATION FAILURE		Recovered without sequelae
0087092	CLARITIN System Organ Class: RESPIRATORY SYSTEM DISORDERS	38 Year(s)	Male		03 Month(s)	Suspected WHO Adverse Reaction Term: DYSPNOEA	10.00 Milligrams 1 Daily	Recovered without sequelae
0087095	CLARITIN System Organ Class: BODY AS A WHOLE - GENERAL DISORDERS BODY AS A WHOLE - GENERAL DISORDERS SKIN AND APPENDAGES DISORDERS MULTIPLE VITAMINS NOVAMOXIN BENADRYL EPINEPHRINE AEROSOL	4 Year(s)	Female			Suspected WHO Adverse Reaction Term: ALLERGIC REACTION OEDEMA SKIN DISORDER Concomitant Concomitant Treatment Treatment	5.00 Milligrams 1 Daily 1.00 Dosage form 1000 Milligrams 25.00 Milligrams	Recovered without sequelae

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0087320	CLARITIN System Organ Class: SKIN AND APPENDAGES DISORDERS BODY AS A WHOLE - GENERAL DISORDERS BENADRYL		Female		02 Day(s)	Suspected Treatment	10.00 Milligrams WHO Adverse Reaction Term: RASH THERAPEUTIC RESPONSE DECREASED 50.00 Milligrams	Recovered without sequelae
0087354	CLARITIN EXTRA System Organ Class: PSYCHIATRIC DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS	20 Year(s)	Male			Suspected	1.00 Dosage form 2 Daily WHO Adverse Reaction Term: ANXIETY NAUSEA	Recovered without sequelae
0087470	CLARITIN EXTRA System Organ Class: CARDIOVASCULAR DISORDERS, GENERAL MUSCULO-SKELETAL SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS ERYBID	28 Year(s)	Female		01 Day(s) 06 Day(s)	Suspected Concomitant	1.00 Dosage form 1 Daily WHO Adverse Reaction Term: OEDEMA DEPENDENT ARTHRALGIA CHEST DISCOMFORT PARAESTHESIA RESPIRATORY DISORDER STUPOR 1.00 Dosage form As necessary	Recovered without sequelae
0087699	CLARITIN System Organ Class: SKIN AND APPENDAGES DISORDERS		Male			Suspected	10.00 Milligrams WHO Adverse Reaction Term: DERMATITIS EXFOLIATIVE	Not yet recovered

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0087756	CLARITIN System Organ Class: RESPIRATORY SYSTEM DISORDERS SKIN AND APPENDAGES DISORDERS SKIN AND APPENDAGES DISORDERS BENADRYL ATARAX SOLU-CORTEF	64 Year(s)	Female			Suspected WHO Adverse Reaction Term: BRONCHOSPASM PRURITUS RASH Concomitant Treatment Treatment	250.0 Milligrams 3 Daily 50.00 Milligrams As necessary 250.0 Milligrams	Recovered without sequelae
0088174	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS PSYCHIATRIC DISORDERS	39 Year(s)	Male		06 Day(s)	Suspected WHO Adverse Reaction Term: SALIVA INCREASED DYSPHAGIA DISORIENTATION	10.00 Milligrams 1 Daily	Recovered without sequelae
0088175	CLARITIN EXTRA System Organ Class: RESPIRATORY SYSTEM DISORDERS PLATELET,BLEEDING & CLOTTING DISORDERS		Female		01 Day(s)	Suspected WHO Adverse Reaction Term: SINUSITIS PURPURA	1.00 Dosage form 2 Daily	Recovered without sequelae
0088185	CLARITIN System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS	36 Year(s)	Female		01 Day(s)	Suspected WHO Adverse Reaction Term: DIZZINESS	80.00 Milligrams 1 Daily	Recovered without sequelae
0088270	CLARITIN System Organ Class: SPECIAL SENSES OTHER, DISORDERS SPECIAL SENSES OTHER, DISORDERS	47 Year(s)	Female			Suspected WHO Adverse Reaction Term: SMELL ALTERATION TASTE LOSS	2.00 Dosage form 1 Daily	Not yet recovered

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116434	CLARITIN System Organ Class: REPRODUCTIVE DISORDERS, FEMALE	19 Year(s)	Female			Suspected WHO Adverse Reaction Term: LABOUR PREMATURE		Unknown
0116436	CLARITIN System Organ Class: NEONATAL AND INFANCY DISORDERS FOETAL DISORDERS					Suspected WHO Adverse Reaction Term: BIRTH PREMATURE CONGENITAL ANOMALY NOS		Died drug may be contributory
0116751	CLARITIN EXTRA System Organ Class: SKIN AND APPENDAGES DISORDERS SKIN AND APPENDAGES DISORDERS BODY AS A WHOLE - GENERAL DISORDERS VASCULAR (EXTRACARDIAC) DISORDERS HEART RATE AND RHYTHM DISORDERS		Female			Suspected WHO Adverse Reaction Term: ERYTHEMA PRURITUS OEDEMA OF EXTREMITIES FLUSHING PALPITATION	First dose	Recovered without sequelae
0116753	CLARITIN System Organ Class: BODY AS A WHOLE - GENERAL DISORDERS		Male			Suspected WHO Adverse Reaction Term: CHEST PAIN	10 Milligrams Daily	Recovered without sequelae

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116763	BIAXIN System Organ Class: HEART RATE AND RHYTHM DISORDERS CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS APO-ENALAPRIL BIQUIN DURULES LOSEC ADENOSINE	71 Year(s)	Female		Continuing on Drug Continuing on Drug Continuing on Drug	Suspected WHO Adverse Reaction Term: TACHYCARDIA SUPRAVENTRICULAR Suspected WHO Adverse Reaction Term: TACHYCARDIA SUPRAVENTRICULAR Concomitant Concomitant Concomitant Treatment	250 Milligrams 2 Daily 1 Dosage form Daily 5 Milligrams Daily 250 Milligrams 3 Daily 20 Milligrams Daily	Recovered without sequelae
0116764	CLARITIN EXTRA System Organ Class: CARDIOVASCULAR DISORDERS, GENERAL PSYCHIATRIC DISORDERS HEART RATE AND RHYTHM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS DIMETAPP OTRIVIN	11 Year(s)	Female		2 Day(s)	Suspected WHO Adverse Reaction Term: HYPERTENSION CATATONIC REACTION TACHYCARDIA SYNCOPE Concomitant Concomitant	1 Dosage form Daily	Recovered without sequelae
0116770	CLARITIN System Organ Class: HEART RATE AND RHYTHM DISORDERS					Suspected WHO Adverse Reaction Term: TACHYCARDIA VENTRICULAR		Unknown

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116830	CLARITIN	80 Year(s)	Female		~2 Month(s)	Suspected	10 Milligrams As necessary	Unknown
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	RESPIRATORY SYSTEM DISORDERS					PNEUMONIA		
	HEART RATE AND RHYTHM DISORDERS					TORSADE DE POINTES		
	RESPIRATORY SYSTEM DISORDERS					HYPOXAEMIA		
	METABOLIC AND NUTRITIONAL DISORDERS					HYPOKALAEMIA		
	METABOLIC AND NUTRITIONAL DISORDERS					HYPONATRAEMIA		
	METABOLIC AND NUTRITIONAL DISORDERS					HYPERGLYCAEMIA		
	ASPIRIN CHILDRENS					Concomitant	80 Milligrams Daily	
	BONAMINE					Concomitant	25 Milligrams 3 Daily	
	BRICANYL					Concomitant	0.5 Milligrams 4 Daily	
	PACEMAKER					Concomitant		
	PULMICORT					Concomitant	2 Dosage form 4 Daily	
	RESTORIL					Concomitant	15 Milligrams Daily	
	SYNTHROID					Concomitant	0.1 Milligrams Daily	
	THEO-DUR					Concomitant	200 Milligrams 2 Daily	
	CIPRO					Other		
	ERYTHROMYCIN					Other		
	FLOVENT					Other		
	VENTOLIN					Other		
	LIDOCAINE					Treatment		
0116843	CLARITIN	50 Year(s)	Female		Continuing on Drug	Suspected	10 Milligrams Daily	Not yet recovered
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	BODY AS A WHOLE - GENERAL DISORDERS					PAIN		
	GASTRO-INTESTINAL SYSTEM DISORDERS					TOOTH ACHE		

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116844	CLARITIN EXTRA System Organ Class: PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS PSYCHIATRIC DISORDERS	-	Female		6 Day(s)	Suspected	1 Dosage form Daily	Recovered without sequelae
0116846	CLARITIN EXTRA System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS	-	Female		3 Day(s)	Suspected	1 Dosage form 2 Daily	Not yet recovered
0116848	CLARITIN System Organ Class: GASTRO-INTESTINAL SYSTEM DISORDERS SKIN AND APPENDAGES DISORDERS	67 Year(s)	Female		Continuing on Drug	Suspected		Not yet recovered
0116882	CLARITIN System Organ Class: RESPIRATORY SYSTEM DISORDERS BECLOFORTE VENTOLIN	37 Year(s)	Female			Suspected Concomitant Concomitant	10 Milligrams First dose WHO Adverse Reaction Term: BRONCHOSPASM	Recovered without sequelae

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117178	CLARITIN EXTRA <i>System Organ Class:</i> SKIN AND APPENDAGES DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS APPLICATION SITE DISORDERS SUDAFED <i>System Organ Class:</i> CENTR & PERIPH NERVOUS SYSTEM DISORDERS SKIN AND APPENDAGES DISORDERS APPLICATION SITE DISORDERS PREDNISONE	40 Year(s)	Male		2 Day(s)	Suspected Suspected Treatment	1 Dosage form 2 Daily <i>WHO Adverse Reaction Term:</i> RASH ERYTHEMATOUS BURNING SKIN SKIN NECROSIS 1 Dosage form 2 Daily <i>WHO Adverse Reaction Term:</i> BURNING SKIN RASH ERYTHEMATOUS SKIN NECROSIS	Recovered without sequelae
0117232	LORATADINE <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS ERYTHROMYCIN ETHYLSUCCINA	47 Year(s)	Male			Suspected Concomitant	10 Milligrams Daily <i>WHO Adverse Reaction Term:</i> PALPITATION	Recovered without sequelae
0117233	CLARITIN <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS VENTOLIN <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS COUMADIN LOPRESOR MODURET PREMARIN PROVERA SYNTHROID ZOCOR PROPAFENONE	83 Year(s)	Female		4.5 Year(s) Continuing on Drug Continuing on Drug Continuing on Drug Continuing on Drug Continuing on Drug	Suspected Suspected Concomitant Concomitant Concomitant Concomitant Concomitant Concomitant Concomitant Treatment	As necessary <i>WHO Adverse Reaction Term:</i> AURICULAR FIBRILLATION As necessary <i>WHO Adverse Reaction Term:</i> AURICULAR FIBRILLATION 1 Milligrams Daily 200 Milligrams Daily 1 Dosage form Daily 0.625 Milligrams Daily 112 Micrograms Daily 10 Milligrams Daily	Recovered without sequelae

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Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117491	CLARITIN EXTRA System Organ Class: PLATELET,BLEEDING & CLOTTING DISORDERS PLATELET,BLEEDING & CLOTTING DISORDERS COUMADIN System Organ Class: PLATELET,BLEEDING & CLOTTING DISORDERS PLATELET,BLEEDING & CLOTTING DISORDERS ASPIRIN	46 Year(s)	Male		2 Day(s)	Suspected WHO Adverse Reaction Term: HAEMORRHAGE NOS BRUISE Suspected WHO Adverse Reaction Term: BRUISE HAEMORRHAGE NOS Concomitant	2 Daily 7 Milligrams 1 Daily 80 Milligrams 1 Daily	Not yet recovered
0117726	CLARITIN System Organ Class: BODY AS A WHOLE - GENERAL DISORDERS PSYCHIATRIC DISORDERS BODY AS A WHOLE - GENERAL DISORDERS		Male			Suspected WHO Adverse Reaction Term: TEMPERATURE BODY DECREASE NERVOUSNESS SHIVERING	10 Milligrams Daily	Recovered without sequelae
0117831	CLARITIN System Organ Class: RESPIRATORY SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS SKIN AND APPENDAGES DISORDERS BENADRYL CORTICOSTEROID(S) EPINEPHRINE	49 Year(s)	Female		Continuing on Drug	Suspected WHO Adverse Reaction Term: DYSPNOEA ANAPHYLACTOID REACTION PRURITUS Treatment Treatment Treatment	10 Milligrams 1 Daily	Recovered without sequelae
0118355	CLARITIN EXTRA System Organ Class: URINARY SYSTEM DISORDERS	37 Year(s)	Male		1 Month(s)	Suspected WHO Adverse Reaction Term: URINARY RETENTION	2 Dosage form Daily	Recovered without sequelae

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Lorafadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118690	CLARITIN System Organ Class: SKIN AND APPENDAGES DISORDERS FLONASE System Organ Class: SKIN AND APPENDAGES DISORDERS ATROVENT BECLOFORTE DIGOXIN ENALAPRIL FUROSEMIDE POTASSIUM CHLORIDE	83 Year(s)	Female		Continuing on Drug Continuing on Drug	Suspected Suspected Concomitant Concomitant Concomitant Concomitant Concomitant Concomitant	 WHO Adverse Reaction Term: SKIN DISCOLOURATION WHO Adverse Reaction Term: SKIN DISCOLOURATION	Not yet recovered
0118704	CLARITIN System Organ Class: BODY AS A WHOLE - GENERAL DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS MUSCULO-SKELETAL SYSTEM DISORDERS PROZAC THYROID ACUPUNCTURE		Female		1-3 Month(s)	Suspected Concomitant Concomitant Treatment	10 Milligrams Daily WHO Adverse Reaction Term: PAIN LEGS WALKING DIFFICULTY MUSCLE ACHE	Not yet recovered
0119322	CLARITIN System Organ Class: FOETAL DISORDERS	34 Year(s)	Female		3 Day(s)	Suspected	10 Milligrams 1 Daily WHO Adverse Reaction Term: DEATH FOETAL	Unknown

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:31AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0120082	CLARITIN <i>System Organ Class:</i> PSYCHIATRIC DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS	30 Year(s)	Male		5 Day(s)	Suspected	10 Milligrams 1 Daily	
	IMODIUM <i>System Organ Class:</i> PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS				Continuing on Drug	Suspected	2 Milligrams 1 Daily	
0120317	CLARITIN EXTRA <i>System Organ Class:</i> REPRODUCTIVE DISORDERS, FEMALE	38 Year(s)	Female		10 Day(s)	Suspected	1 Daily	Recovered without sequelae
	CALCIUM CARBONATE				Continuing on Drug	Concomitant	Daily	
	MULTIVITAMINS WITH MINERAL				Continuing on Drug	Concomitant	Daily	
	VITAMIN E				Continuing on Drug	Concomitant	400 International units Daily	
0120380	CLARITIN EXTRA <i>System Organ Class:</i> REPRODUCTIVE DISORDERS, FEMALE MUSCULO-SKELETAL SYSTEM DISORDERS	25 Year(s)	Female		~5 Month(s)	Suspected	2 Daily	Recovered without sequelae
	MULTIPLE VITAMINS					Concomitant	Daily	
	ORTHO 1/35					Concomitant	Daily	
0120981	CLARITIN <i>System Organ Class:</i> GASTRO-INTESTINAL SYSTEM DISORDERS PSYCHIATRIC DISORDERS	2 Year(s)	Female			Suspected	10 Milligrams First dose	Unknown
							<i>WHO Adverse Reaction Term:</i> VOMITING DROWSINESS	

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April 12, 1999

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APR 13 '99 14:38 FR B DRUG SURVEILLANCE 613 957 0335 TO 18187126482

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Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0121441	CLARITIN <i>System Organ Class:</i> PSYCHIATRIC DISORDERS BODY AS A WHOLE - GENERAL DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS TYLENOL TYLENOL ELIXIR	2 Year(s)	Female		Continuing on Drug Continuing on Drug	Suspected <i>WHO Adverse Reaction Term:</i> LETHARGY FEVER STOMATITIS Concomitant Concomitant	2.5 Millilitres 2 Daily 1 Teaspoonful 5 Millilitres ~5 Daily	Recovered without sequelae Unknown
0121676	CLARITIN <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS BENADRYL METHIMAZOLE PROPRANOLOL HYDROCHLORID	13 Year(s)	Male			Suspected <i>WHO Adverse Reaction Term:</i> QT PROLONGED Concomitant Concomitant Concomitant	15 Milligrams Daily 30 Milligrams 3 Daily	
0121786	CLARITIN <i>System Organ Class:</i> BODY AS A WHOLE - GENERAL DISORDERS		Female			Suspected <i>WHO Adverse Reaction Term:</i> EFFICACY, LACK OF	10 Milligrams Daily	Recovered without sequelae
0121788	CEFTIN <i>System Organ Class:</i> GASTRO-INTESTINAL SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS CLARITIN <i>System Organ Class:</i> GASTRO-INTESTINAL SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS HYDRATATION METRONIDAZOLE	54 Year(s)	Female			Suspected <i>WHO Adverse Reaction Term:</i> DIARRHOEA CRAMP ABDOMINAL Suspected <i>WHO Adverse Reaction Term:</i> DIARRHOEA CRAMP ABDOMINAL Treatment Treatment	250 Milligrams 2 Daily 2 Daily	Recovered without sequelae

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APR 13 '99 14:39 FR B DRUG SURVEILLANCE 613 957 0335 TO 18187126482

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RECEIVED TIME APR.13. 11:31AM

Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Suspected Drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0121790	CLARITIN		Male			Suspected		Unknown
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	RESPIRATORY SYSTEM DISORDERS					THROAT IRRITATION		
	RESPIRATORY SYSTEM DISORDERS					THROAT SORE		
	RESPIRATORY SYSTEM DISORDERS					COUGHING		
	BODY AS A WHOLE - GENERAL DISORDERS					CONDITION AGGRAVATED		
0121791	CLARITIN		Female			Suspected		Unknown
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	BODY AS A WHOLE - GENERAL DISORDERS					FEVER		
	GASTRO-INTESTINAL SYSTEM DISORDERS					DIARRHOEA		
	GASTRO-INTESTINAL SYSTEM DISORDERS					BLOATING		
	GASTRO-INTESTINAL SYSTEM DISORDERS					ABDOMINAL PAIN LOWER		
	MUSCULO-SKELETAL SYSTEM DISORDERS					CRAMPS		
0121807	CLARITIN	69 Year(s)	Female			Suspected	5 Milligrams 2 Daily	Recovered without sequelae
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	CARDIOVASCULAR DISORDERS, GENERAL					BLOOD PRESSURE HIGH		
	ENALAPRIL			Continuing on Drug		Concomitant	5 Milligrams Daily	
	TAMOXIFEN			Continuing on Drug		Concomitant	20 Milligrams Daily	
	VITAMINS			Continuing on Drug		Concomitant		
0121869	CLARITIN	10 Year(s)	Male		2 Day(s)	Suspected	10 Milligrams Daily	Recovered without sequelae
	<i>System Organ Class:</i>					<i>WHO Adverse Reaction Term:</i>		
	SKIN AND APPENDAGES DISORDERS					RASH		

Total No. of reports 94

Total No. of reports with fatal outcome 2

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** TOTAL PAGE. 24 **

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Health Santé
Canada Canada

Part I: 23 pages + this one
This is —————> Part II: 19 pages + this one
Part III: 19 pages + this one.



PROGRAMME DES
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PROGRAMME

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

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FINANCE BUILDING / ÉDIFICE FINANCE
FIRST FLOOR / 1^{er} ÉTAGE
OTTAWA (ONTARIO)
K1A 1B9
ADDRESS LOCATOR -0201C1 - INDICE DE L'ADRESSE
FAX: (613) 957-0335

TO/À: Robert Seidman

FAX: 1(818) 712-6482

TEL: (818) 610-4817

DATE: April 13, 1999

NUMBER OF PAGES TO FOLLOW: 61
NOMBRE DE PAGES À SUIVRE:

MESSAGE/MESSAGE:

Dear Mr. Seidman,

This is further to your fax dated December 16, 1998 requesting information on suspected adverse drug reactions (ADRs) associated with the use of cetirizine, fexofenadine and loratadine. We apologize for the delay.

A search of the national database was performed for all the suspected adverse reactions associated with these suspected drugs. The attached printouts outline the results. These printouts cover the time period since marketing until April 12, 1999. There may be reports which have been received by the program which are not yet entered into the database. Kindly direct your attention of all persons using these printouts to the following Caveat:

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Protection Branch is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Protection Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization.

If you have any further questions, please do not hesitate to contact me.

Pascale Springuel

RECEIVED TIME APR.13. 11:42AM

Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine - "Interaction - Food"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:42AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0088173	CLARITIN	-	Female		01 Day(s)	Interaction -Food	10.00 Milligrams 1 Daily	Not yet recovered
	System Organ Class:					WHO Adverse Reaction Term:		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					COMA		
	BODY AS A WHOLE - GENERAL DISORDERS					ANAPHYLACTIC REACTION		
	FOOD REACTIONS					Interaction -Food		
	System Organ Class:					WHO Adverse Reaction Term:		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					COMA		
	BODY AS A WHOLE - GENERAL DISORDERS					ANAPHYLACTIC REACTION		

Total No. of reports 1

Total No. of reports with fatal outcome

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April 12, 1999

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APR 13 '99 14:42 FR B DRUG SURVEILLANCE 613 957 0335 TO 18186104817

P.02/20

Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine as "Interaction drug"
All Reports received and entered into database before April 12, 1999

Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
CENTRAL NERVOUS SYSTEM DISORDERS	03 Day(s) Continuing on Drug	Interaction -Drug	10.00 Milligrams 1 Daily	Recovered without sequelae
		WHO Adverse Reaction Term:		
		MIGRAINE		
CENTRAL NERVOUS SYSTEM DISORDERS		Concomitant	1.00 Dosage form 1 Daily	
		Interaction -Drug	1.00 Dosage form 1 Daily	Recovered with sequelae
		WHO Adverse Reaction Term:		
CENTRAL NERVOUS SYSTEM DISORDERS		HEARING IMPAIRED		
		CONDITION AGGRAVATED		
		TINNITUS		
CENTRAL NERVOUS SYSTEM DISORDERS		Interaction -Drug	1.00 Dosage form 2 Daily	
		WHO Adverse Reaction Term:		
		CONDITION AGGRAVATED		
CENTRAL NERVOUS SYSTEM DISORDERS		CONDITION AGGRAVATED		
		TINNITUS		
		CONDITION AGGRAVATED		
CENTRAL NERVOUS SYSTEM DISORDERS		TINNITUS		
		HEARING IMPAIRED		
		TINNITUS		
CENTRAL NERVOUS SYSTEM DISORDERS		HEARING IMPAIRED		
		HEARING IMPAIRED		
		Interaction -Drug		
CENTRAL NERVOUS SYSTEM DISORDERS		WHO Adverse Reaction Term:		
		CONDITION AGGRAVATED		
		CONDITION AGGRAVATED		
CENTRAL NERVOUS SYSTEM DISORDERS		HEARING IMPAIRED		
		HEARING IMPAIRED		
		TINNITUS		
CENTRAL NERVOUS SYSTEM DISORDERS		TINNITUS		

This summary is based on reports submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, but effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports is not scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted to the Canadian Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

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P.03/20

Case report number	Drug name	Age	Sex
72628	CLARITIN	25 Year(s)	Female
	<i>System Organ Class:</i> CENTR & PERIPH NERVOUS S		
	OVRAL		
080689	CLARITIN	49 Year(s)	Female
	<i>System Organ Class:</i> HEARING AND VESTIBULAR BODY AS A WHOLE - GENER		
	HEARING AND VESTIBULAR		
	SELDANE		
	<i>System Organ Class:</i> BODY AS A WHOLE - GENER		
	BODY AS A WHOLE - GENER		
	HEARING AND VESTIBULAR		
	BODY AS A WHOLE - GENER		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		
	TAGAMET		
	<i>System Organ Class:</i> BODY AS A WHOLE - GENER		
	BODY AS A WHOLE - GENER		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		
	HEARING AND VESTIBULAR		

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine as "Interaction drug"
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0084173		70 Year(s)	Female					
	CLARITIN					Interaction -Drug	10.00 Milligrams	
	System Organ Class:					WHO Adverse Reaction Term:		
	CARDIOVASCULAR DISORDERS, GENERAL					ECG ABNORMAL SPECIFIC		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA ATRIAL		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA VENTRICULAR		
	GRAVOL					Interaction -Drug	3.00 Grams	
	System Organ Class:					WHO Adverse Reaction Term:		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA ATRIAL		
	CARDIOVASCULAR DISORDERS, GENERAL					ECG ABNORMAL SPECIFIC		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA VENTRICULAR		
	COUMADIN					Concomitant	2.50 Milligrams	
	LANOXIN					Concomitant	0.25 Milligrams	
	LASIX					Concomitant	20.00 Milligrams	
0084437		20 Year(s)	Female					
	CECLOR				06 Day(s)	Interaction -Drug	750.0 Milligrams 1 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	HEART RATE AND RHYTHM DISORDERS					PALPITATION		
	BODY AS A WHOLE - GENERAL DISORDERS					CHEST PAIN		
	BODY AS A WHOLE - GENERAL DISORDERS					SYNCOPE		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA		
	CLARITIN				10 Day(s)	Interaction -Drug	10.00 Milligrams 1 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	BODY AS A WHOLE - GENERAL DISORDERS					CHEST PAIN		
	HEART RATE AND RHYTHM DISORDERS					PALPITATION		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA		
	BODY AS A WHOLE - GENERAL DISORDERS					SYNCOPE		

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April 12, 1999

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APR 13 '99 14:42 FR B DRUG SURVEILLANCE 613 957 0335 TO 18186104817

P.04/20

Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine as "Interaction drug"
All Reports received and entered into data base before April 12, 1999

RECEIVED TIME APR. 13. 11:42AM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086653	CLARITIN System Organ Class: PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS PSYCHIATRIC DISORDERS	3 Year(s)	Female		03 Week(s)	Interaction -Drug	5.00 Milligrams 1 Daily	Recovered with sequelae
	INTAL				23 Day(s)	Concomitant	3.00 Dosage form 3 Daily	
0087094	CLARITIN System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS MUSCULO-SKELETAL SYSTEM DISORDERS	30 Year(s)	Female			Interaction -Drug	10.00 Milligrams	Recovered without sequelae
	MINOCIN System Organ Class: MUSCULO-SKELETAL SYSTEM DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS RESPIRATORY SYSTEM DISORDERS				06 Day(s)	Interaction -Drug	150.0 Milligrams	
0087319	CLARITIN EXTRA System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS		Female			Interaction -Drug	2.00 Dosage form	Recovered without sequelae
	MANERIX System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS					Interaction -Drug	300.0 Milligrams 2 Daily	
	CLARITIN					Other	As necessary	

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April 12, 1999

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APR 13 '99 14:43 FR B DRUG SURVEILLANCE 613 957 0335 TO 18186104817

P.05/20

Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Loratadine as "Interaction drug"
All Reports received and entered into database before April 12, 1999

RECEIVED TIME APR. 13. 11:42PM

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0087961	CLARITIN		Male		Continuing on Drug	Interaction -Drug	10.00 Milligrams	
	System Organ Class:					WHO Adverse Reaction Term:		
	BODY AS A WHOLE - GENERAL DISORDERS					UNEXPECTED THERAPEUTIC EFFECT		
	PROZAC				Continuing on Drug	Interaction -Drug		
	System Organ Class:					WHO Adverse Reaction Term:		
	BODY AS A WHOLE - GENERAL DISORDERS					UNEXPECTED THERAPEUTIC EFFECT		
0118505	CLARITIN EXTRA	46 Year(s)	Male		2 Day(s)	Interaction -Drug	1 Dosage form 2 Daily	Unknown
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					HAEMORRHAGIC DISORDER		
	COUMADIN				Continuing on Drug	Interaction -Drug	7 Milligrams Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					HAEMORRHAGIC DISORDER		
	ASPIRIN CHILDRENS				Continuing on Drug	Concomitant	1 Dosage form 1 Daily	
0119061	CLARITIN EXTRA	45 Year(s)	Male		2 Day(s)	Interaction -Drug	1 Dosage form 2 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	SKIN AND APPENDAGES DISORDERS					RASH HAEMORRHAGIC		
	COUMADIN				Continuing on Drug	Interaction -Drug	5 Milligrams 1 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	SKIN AND APPENDAGES DISORDERS					RASH HAEMORRHAGIC		
	ASPIRIN CHILDRENS				Continuing on Drug	Concomitant	1 Dosage form 1 Daily	

Total No. of reports 10

Total No. of reports with fatal outcome

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April 12, 1999

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P.06/20

Canadian Adverse Drug Reaction Monitoring Program

Summary of Reported Adverse Drug Reactions

Active Ingredient: Cetirizine

All Reports received and entered into database before April 12, 1999

Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
		Suspected WHO Adverse Reaction Term: VISION ABNORMAL	10.00 Milligrams	
		Suspected WHO Adverse Reaction Term: PARAESTHESIA DROWSINESS	10.00 Milligrams	Recovered without sequelae
S SYSTEM DISORDERS		Concomitant Concomitant Concomitant	500.0 Milligrams	
		Suspected WHO Adverse Reaction Term: SOMNOLENCE	10.00 Milligrams	
		Concomitant		
TEM DISORDERS S SYSTEM DISORDERS		Suspected WHO Adverse Reaction Term: MYALGIA MUSCLE STIFFNESS	10.00 Milligrams	
		Suspected WHO Adverse Reaction Term: THROMBOCYTOPENIA	10.00 Milligrams	
LOTING DISORDERS		Suspected WHO Adverse Reaction Term: CONVULSIONS		
S SYSTEM DISORDERS				

is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, Effect relationships have not been established in the vast majority of reports submitted. The information contained in these en scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small ogram, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted This summary contains unpublished data and is provided to you with the understanding that this data will be used only rug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

April 12, 1999

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P.07/20

Case report number	Drug name	Age	Sex
78629	REACTINE <i>System Organ Class:</i> VISION DISORDERS	42 Year(s)	Female
78825	REACTINE <i>System Organ Class:</i> CENTR & PERIPH NERVOUS S PSYCHIATRIC DISORDERS ALLBEE WITH C ALLERGY INJECTION TYLENOL	43 Year(s)	Female
30966	REACTINE <i>System Organ Class:</i> PSYCHIATRIC DISORDERS HYDROXYZINE	29 Year(s)	Female
081394	REACTINE <i>System Organ Class:</i> MUSCULO-SKELETAL SYSTE CENTR & PERIPH NERVOUS S	-	Male
086041	REACTINE <i>System Organ Class:</i> PLATELET, BLEEDING & CLO	4 Year(s)	Female
086042	REACTINE <i>System Organ Class:</i> CENTR & PERIPH NERVOUS S	25 Year(s)	Male

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0086043	REACTINE <i>System Organ Class:</i> BODY AS A WHOLE - GENERAL DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS PROVERA	53 Year(s)	Female			Suspected <i>WHO Adverse Reaction Term:</i> WITHDRAWAL SYNDROME WITHDRAWAL HEADACHE Concomitant	5.00 Milligrams	
0086300	REACTINE <i>System Organ Class:</i> GASTRO-INTESTINAL SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS	34 Year(s)	Female			Suspected <i>WHO Adverse Reaction Term:</i> NAUSEA WITHDRAWAL SYNDROME VOMITING SPUTUM INCREASED	10.00 Milligrams	Recovered without sequelae
0086454	REACTINE <i>System Organ Class:</i> SKIN AND APPENDAGES DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS SKIN AND APPENDAGES DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS HEART RATE AND RHYTHM DISORDERS PSYCHIATRIC DISORDERS		Female			Suspected <i>WHO Adverse Reaction Term:</i> SWEATING INCREASED FAECAL ABNORMALITY NOS SKIN COLD CLAMMY MIGRAINE AGGRAVATED CHEST PAIN ARRHYTHMIA ANXIETY	10.00 Milligrams 2 Daily	Recovered without sequelae
0086660	REACTINE <i>System Organ Class:</i> SKIN AND APPENDAGES DISORDERS	19 Year(s)	Female			Suspected <i>WHO Adverse Reaction Term:</i> URTICARIA	10.00 Milligrams 1 Daily	Recovered without sequelae

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0088178	REACTINE <i>System Organ Class:</i> CARDIOVASCULAR DISORDERS, GENERAL RESPIRATORY SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS ANTIBIOTIC(S) ACETYLSALICYLIC ACID ENT CT ATENOLOL HEPARIN NITROGLYCERIN	55 Year(s)	Male			Suspected <i>WHO Adverse Reaction Term:</i> HEART DISORDER DYSPNOEA CHEST TIGHTNESS OF Concomitant Treatment Treatment Treatment Treatment		Recovered without sequelae
0088803	PROZAC <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS HEART RATE AND RHYTHM DISORDERS REACTINE <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS HEART RATE AND RHYTHM DISORDERS	30 Year(s)	Female		05 Day(s) 13 Day(s)	Suspected <i>WHO Adverse Reaction Term:</i> DYSPNOEA TACHYCARDIA Suspected <i>WHO Adverse Reaction Term:</i> DYSPNOEA TACHYCARDIA	1.00 Dosage form 1 Daily 1.00 Dosage form 1 Daily	Recovered without sequelae
0116754	REACTINE <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS PSYCHIATRIC DISORDERS CENTR & PERIPH NERVOUS SYSTEM DISORDERS PSYCHIATRIC DISORDERS PSEUDOEPHEDRINE HCL	14 Year(s)	Female			Suspected <i>WHO Adverse Reaction Term:</i> TACHYCARDIA SUICIDE ATTEMPT TREMOR SOMNOLENCE Concomitant	120 Milligrams First dose 360 Milligrams First dose	Unknown

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116771	REACTINE <i>System Organ Class:</i> BODY AS A WHOLE - GENERAL DISORDERS VASCULAR (EXTRACARDIAC) DISORDERS BODY AS A WHOLE - GENERAL DISORDERS LOSEC PLENDIL PREPULSID	61	Female		26 Day(s) Continuing on Drug	Suspected <i>WHO Adverse Reaction Term:</i> RIGORS FLUSHING MALAISE Concomitant Concomitant Other	10 Milligrams Daily 20 Milligrams Daily 10 Milligrams Daily 20 Milligrams 2 Daily	Recovered with sequelae
0116801	REACTINE <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS RENEDIL <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS ACETAMINOPHEN	68 Year(s)	Female			Suspected <i>WHO Adverse Reaction Term:</i> PALPITATION Suspected <i>WHO Adverse Reaction Term:</i> PALPITATION Concomitant	10 Milligrams First dose 5 Milligrams Daily 1000 Milligrams Daily	Recovered without sequelae
0116802	REACTINE <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS CARDIOVASCULAR DISORDERS, GENERAL SKIN AND APPENDAGES DISORDERS	40 Year(s)	Female		1 Day(s)	Suspected <i>WHO Adverse Reaction Term:</i> BREATHING DIFFICULT HYPOTENSION URTICARIA ACUTE	10 Milligrams First dose	Recovered without sequelae

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116820	LAMISIL <i>System Organ Class:</i> HEART RATE AND RHYTHM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS VASCULAR (EXTRACARDIAC) DISORDERS REACTINE <i>System Organ Class:</i> GASTRO-INTESTINAL SYSTEM DISORDERS VASCULAR (EXTRACARDIAC) DISORDERS HEART RATE AND RHYTHM DISORDERS	38 Year(s)	Female		4-5 Day(s)	Suspected <i>WHO Adverse Reaction Term:</i> PALPITATION NAUSEA FLUSHING Suspected <i>WHO Adverse Reaction Term:</i> NAUSEA FLUSHING PALPITATION	5 Milligrams	Recovered without sequelae
0116842	REACTINE <i>System Organ Class:</i> SKIN AND APPENDAGES DISORDERS BODY AS A WHOLE - GENERAL DISORDERS	11 Year(s)	Male		1 Day(s)	Suspected <i>WHO Adverse Reaction Term:</i> HIVES CONDITION AGGRAVATED	10 Milligrams Daily	Recovered without sequelae
0116847	REACTINE <i>System Organ Class:</i> CENTR & PERIPH NERVOUS SYSTEM DISORDERS	44 Year(s)	Male		24 Hours(s)	Suspected <i>WHO Adverse Reaction Term:</i> CONVULSIONS	10 Milligrams Daily	Not yet recovered
0116849	REACTINE <i>System Organ Class:</i> LIVER AND BILIARY SYSTEM DISORDERS ACETAMINOPHEN AMITRIPTYLINE NIZATIDINE TERFENADINE	50 Year(s)	Female		2 Year(s) Continuing on Drug Continuing on Drug Continuing on Drug	Suspected <i>WHO Adverse Reaction Term:</i> LIVER ENLARGEMENT Concomitant Concomitant Concomitant Other	10 Milligrams Daily	Unknown

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116850	REACTINE <i>System Organ Class:</i> BODY AS A WHOLE - GENERAL DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS BODY AS A WHOLE - GENERAL DISORDERS GASTRO-INTESTINAL SYSTEM DISORDERS CORTICOSTEROID(S) GAVISCON		Female			Suspected Treatment Treatment	10 Milligrams Daily <i>WHO Adverse Reaction Term:</i> EFFICACY, LACK OF ABDOMINAL PAIN HYPERALIVATION CONDITION AGGRAVATED DIARRHOEA	Recovered without sequelae
0116883	REACTINE <i>System Organ Class:</i> CENTR & PERIPH NERVOUS SYSTEM DISORDERS PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS SABRIL TEGRETOL	11 Year(s)	Male		3 Week(s)	Suspected Concomitant Concomitant	5 Milligrams Daily <i>WHO Adverse Reaction Term:</i> APHASIA MOTOR LETHARGY SOCIAL DEGENERATION	Unknown

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117113			Female					Unknown
	BRICANYL					Suspected	Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		
	FLONASE					Suspected	4 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		
	FLOVENT					Suspected		
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		
	PREPULSID					Suspected	2 Dosage form Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		
	REACTINE					Suspected	3 Weekly	
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		
	SALBUVENT					Suspected	400 Micrograms Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		
	VITAMIN C					Suspected	500 Milligrams	
	System Organ Class:					WHO Adverse Reaction Term:		
	FOETAL DISORDERS					MISCARRIAGE		

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CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

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Case report number	Drug name	Age	Sex
7139	REACTINE	70 Year(s)	Male
	<i>System Organ Class:</i>		
	URINARY SYSTEM DISORDERS		
	BODY AS A WHOLE - GENERAL DISORDERS		
	SKIN AND APPENDAGES DISORDERS		
	ATASOL FORTE		
	ATROVENT		
	ENTROPHEN		
	IMODIUM		
	TRILAFON		
8124	REACTINE	31 Year(s)	Male
	<i>System Organ Class:</i>		
	CENTRAL & PERIPHERAL NERVOUS SYSTEM DISORDERS		
	METABOLIC AND NUTRITIONAL DISORDERS		
	METABOLIC AND NUTRITIONAL DISORDERS		
	PSYCHIATRIC DISORDERS		
	CENTRAL & PERIPHERAL NERVOUS SYSTEM DISORDERS		
	ACETAMINOPHEN WITH CODEINE		
	FLUTICASONE		
	FLUVOXAMINE		
	INSULIN N		
	INSULIN R		
	SODIUM CROMOGLYCAT		
	ZOPICLONE		

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118284	REACTINE System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS BENADRYL HISMANAL SELDANE	26 Year(s)	Female			Suspected WHO Adverse Reaction Term: HEADACHE Other Other Other	10 Milligrams Daily	Unknown
0118536	REACTINE System Organ Class: CENTR & PERIPH NERVOUS SYSTEM DISORDERS DILANTIN	27 Year(s)	Female		2 Day(s) Continuing on Drug	Suspected WHO Adverse Reaction Term: CONVULSIONS Concomitant	40 Milligrams Daily 350 Milligrams Daily	Recovered without sequelae
0118702	REACTINE System Organ Class: COLLAGEN DISORDERS COLLAGEN DISORDERS		Female			Suspected WHO Adverse Reaction Term: LUPUS ERYTHEMATOSUS SYSTEMIC ANTINUCLEAR FACTOR TEST POSITIVE	Daily	Unknown
0118890	ZYRTEC System Organ Class: PSYCHIATRIC DISORDERS	45 Year(s)	Female		same day	Suspected WHO Adverse Reaction Term: SLEEPINESS	10 Milligrams First dose	Recovered without sequelae

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

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Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0119202	REACTINE <i>System Organ Class:</i> PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS PSYCHIATRIC DISORDERS BODY AS A WHOLE - GENERAL DISORDERS PSYCHIATRIC DISORDERS MARVELON FLONASE AMITRIPTYLINE ATIVAN SUBL		Female		5-6 Day(s)	Suspected <i>WHO Adverse Reaction Term:</i> PANIC REACTION ANXIETY REACTION PARANOID REACTION HOT FLUSHES INSOMNIA Concomitant Other Treatment Treatment	10 Milligrams Daily Daily 25 Milligrams Daily 1 Milligrams As necessary	Not yet recovered
0119494	REACTINE <i>System Organ Class:</i> BODY AS A WHOLE - GENERAL DISORDERS HEART RATE AND RHYTHM DISORDERS HEART RATE AND RHYTHM DISORDERS LOSEC PREMARIN PULMICORT VENTOLIN ZOPICLONE CLARITIN	57 Year(s)	Female		7 Day(s) Continuing on Drug Continuing on Drug Continuing on Drug Continuing on Drug Continuing on Drug	Suspected <i>WHO Adverse Reaction Term:</i> CHEST FULLNESS OF ATRIAL FLUTTER/ FIBRILLATION TACHYCARDIA Concomitant Concomitant Concomitant Concomitant Concomitant Other	10 Milligrams Daily 0.625 Milligrams Daily 7.5 Milligrams Daily	Recovered without sequelae

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**Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine**

All Reports received and entered into database before April 12, 1999

Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
IM DISORDERS (AC) DISORDERS IM DISORDERS S SYSTEM DISORDERS ERAL DISORDERS ERS	1 Day(s)	Suspected	10 Milligrams Daily	Recovered without sequelae
		WHO Adverse Reaction Term:		
		TACHYCARDIA		
		FLUSHING		
		PALPITATION		
ERAL DISORDERS IM DISORDERS IM DISORDERS CT	Week(s)	Suspected	5 Milligrams Every other day	
		WHO Adverse Reaction Term:		
		CHEST PAIN		
		CARDIAC ARREST		
		TORSADE DE POINTES		
IM DISORDERS	2 Day(s)	Concomitant	650 Milligrams 1 Daily	
		Concomitant		
		Concomitant	25 Milligrams 1 Daily	
		Concomitant	30 Milligrams 1 Daily	
		Concomitant	2.6 Milligrams 3 Daily	
ERS, FEMALE	4 Day(s)	Suspected	10 Milligrams Daily	Not yet recovered
		WHO Adverse Reaction Term:		
		ARRHYTHMIA NODAL		
		Suspected	10 Milligrams Daily	Unknown
		WHO Adverse Reaction Term:		
Continuing on Drug		INTERMENSTRUAL BLEEDING		
		Concomitant		

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0122315	BECLOFORTE <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS REACTINE <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS SEREVENT <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS VENTOLIN <i>System Organ Class:</i> RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS RESPIRATORY SYSTEM DISORDERS PULMICORT INHALER		Female			Suspected <i>WHO Adverse Reaction Term:</i> THROAT IRRITATION COUGHING THROAT SORE Suspected 10 Milligrams Daily <i>WHO Adverse Reaction Term:</i> THROAT SORE THROAT IRRITATION COUGHING Suspected 2 Dosage form 2 Daily <i>WHO Adverse Reaction Term:</i> THROAT SORE THROAT IRRITATION COUGHING Suspected As necessary <i>WHO Adverse Reaction Term:</i> THROAT SORE THROAT IRRITATION COUGHING Other 200 Micrograms 2 Daily		Recovered without sequelae
0122316	REACTINE <i>System Organ Class:</i> REPRODUCTIVE DISORDERS, MALE BODY AS A WHOLE - GENERAL DISORDERS BODY AS A WHOLE - GENERAL DISORDERS APPLICATION SITE DISORDERS LIDEX	53 Year(s)	Male			Suspected <i>WHO Adverse Reaction Term:</i> PERINEAL PAIN MALE PAIN CONDITION AGGRAVATED SKIN NODULE Treatment	10 Milligrams Daily	Not yet recovered

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0122320	17 Year(s)	Male						Unknown
	REACTINE					Suspected	10 Milligrams Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					THROMBOCYTOPENIA		
	PLATELET,BLEEDING & CLOTTING DISORDERS					NOSEBLEED		
	PLATELET,BLEEDING & CLOTTING DISORDERS					PETECHIAE		
	VISION DISORDERS					CONJUNCTIVAL HAEMORRHAGE		
	RANITIDINE					Concomitant		
	CORTICOSTEROID(S)					Treatment		
0122322	32 Year(s)	Female						Recovered without sequelae
	CO-TRIMOXAZOLE					Suspected	1 Dosage form 2 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					NOSEBLEED		
	FLONASE					Suspected	2 Dosage form Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					NOSEBLEED		
	REACTINE				Continuing on Drug	Suspected	10 Milligrams Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					NOSEBLEED		
	SUDAFED					Suspected	60 Milligrams 3 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PLATELET,BLEEDING & CLOTTING DISORDERS					NOSEBLEED		
0122324	69 Year(s)	Female						Not yet recovered
	REACTINE					Suspected	5 Milligrams 2 Daily	
	System Organ Class:					WHO Adverse Reaction Term:		
	PSYCHIATRIC DISORDERS					DEPRESSION		
	ATROVENT					Concomitant	Dosage form 3 Daily	
	BECLOFORTE					Concomitant	Dosage form 3 Daily	
	TICLOPIDINE				Continuing on Drug	Concomitant	250 Milligrams 2 Daily	
	VENTOLIN					Concomitant	Dosage form 4 Daily	

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

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Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Cetirizine

All Reports received and entered into database before April 12, 1999

Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
GENERAL DISORDERS GENERAL DISORDERS	1 Day(s)	Suspected WHO Adverse Reaction Term: DEPRESSION	10 Milligrams Daily	Recovered without sequelae
		Suspected WHO Adverse Reaction Term: FATIGUE EXTREME CRYING ABNORMAL BAD MOOD		Unknown
GENERAL DISORDERS GENERAL DISORDERS	2 Week(s)	Suspected WHO Adverse Reaction Term: CONFUSION HYPONATRAEMIA	10 Milligrams Daily	Recovered without sequelae
		Concomitant Concomitant Concomitant Treatment		
Total No. of reports				43
Total No. of reports with fatal outcome				

Information is based on reports submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion of an adverse effect relationship. Effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small number of reports are included in this summary, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted to the Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

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Case report number	Drug name	Age	Sex
122325	REACTINE	40 Year(s)	Male
	System Organ Class: PSYCHIATRIC DISORDERS		
122326	REACTINE	-	Female
	System Organ Class: BODY AS A WHOLE - GENER BODY AS A WHOLE - GENER PSYCHIATRIC DISORDERS		
122495	REACTINE	-	Male
	System Organ Class: PSYCHIATRIC DISORDERS METABOLIC AND NUTRITIC METHOTRIMEPRAZINE MULTIVITAMINE(S) OXAZEPAM NORMAL SALINE		

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** TOTAL PAGE.20 **

CAVEAT: The vast majority of reports on which this summary is
 opinion or observation of the individual reporter. Cause and effect
 reports to the Health Canada is raw information and has not been
 proportion of suspected adverse reactions are reported to the pro-
 y pharmaceutical manufacturers are included in this summary.
 within your immediate organization. Produced by: Adverse Dr